REMARKS

The Office Action of April 16, 2004, has been carefully reviewed. The claims in the application remain as claims 6-14, 16, 19 and 20, and these claims define patentable subject matter warranting their allowance. Accordingly, the applicant respectfully request favorable reconsideration and allowance.

Claims 19 and 20 are rejected as anticipated under S102 by newly cited Lacy et al USP 6,096,338 (Lacy). This rejection is respectfully traversed.

As the rejection correctly states, Lacy discloses "probucol", and also discloses the possible use of gelatin capsules. However, the pending claims 19 and 20 do not cover "probucol"[1]. The drug claimed in the pending claims is only 4,6-di-tert-butyl-2,2-di-n-pentyl-5-hydroxy-2,3-dihydrobenzofuran, i.e. BO-653. As can be seen from the attachments, probucol is greatly different from BO-653 in structure. Such a difference renders it impossible to consider claims 19 and 20 to be anticipated by Lacy.

As Lacy does not anticipate either of claims 19 and 20, applicant respectfully requests withdrawal of the rejection.

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[1] Please note that applicant, in response to the Office Action of October 1, 2002, deleted "probucol" from applicant's claims, and specified "soybean oil" in place of "a fat and oil". Applicant specified only BO-653 in response to the Office Action mailed June 18, 2003.

For the record, applicant does not understand the examiner's comment regarding the recitation in claim 20 that the solution is "substantially free of any other component". Applicant believes that the word "substantially" appears often in U.S. patent claims, and the word "substantially" has been interpreted by the courts many times. Recitation of "substantially free" cannot mean that other components may be present in meaningful quantities.

Claims 6-14, 16, 19 and 20 have been rejected as obvious under §103 from Lacy in view of Amey et al USP 6,080,426 (Amey). This rejection is respectfully traversed.

First, Amey has not been cited to make up for the aforementioned deficiencies of Lacy as pointed out above, and indeed does not do so. Therefore, even if the combination were obvious, such combination would not reach any of applicant's claims.

Moreover, in Lacy, focus is placed on the use of a class of hydrophilic surfactants which do not substantially inhibit the lipolysis of a digestible oil and absorption of a drug. See column 3, lines 37-57. In addition, Lacy describes: "an important feature of the preferred embodiments of the present invention is the selection of a hydrophilic surfactant". See column 4, lines 36-38. No attention is focused on the digestible oil, still less on soybean oil which is merely referred to as an

example of the digestible oils. A person skilled in the art would not have been motivated by Lacy to select soybean oil from all the other digestible oils as a carrier.

In addition, the present invention provides certain unexpected effects which are not achieved when probucol is similarly maintained in a soft gelatin capsule shell. In this regard, please note the attached Declaration of Dr. Katsuki which, in Table A, shows that only 64.6% of BO-653 remains not decomposed under the accelerated decomposing conditions when in the form of raw powder, while 87.9% of the drug remains not decomposed under the same conditions when dissolved in soybean oil, indicating that BO-653 is effectively stabilized by dissolving it in soybean oil. In contrast, probucol is stable both in the form of raw powder and in soybean oil solution under the same conditions, indicating that the combination of probucol with soybean oil does not provide any advantage in terms of stabilization.

Additionally, as can be seen from the description appearing on page 15, lines 14-17 of the specification, BO-653 can be dissolved in soybean oil to a concentration of 10 wt%. In contrast, as indicated in the footnote #2 of Table A set out in the Declaration, probucol is dissolved in soybean oil to a concentration of only up to about 5 wt%. This indicates that

absorption of BO-653 in vivo is greatly improved, as compared to that of probucol, by combining BO-653 with soybean oil.

As stated above, Lacy does not motivate a person skilled in the art to select soybean oil as a carrier. Even if the skilled artisan were motivated to select soybean oil by Lacy, he or she would not conceive combining the oil with BO-653 since neither Lacy nor Amey discloses BO-653 per se, the higher solubility or the improved absorption of drug achieved by combining BO-653 with soybean oil.

Withdrawal of the rejection is in order and is respectfully requested.

Applicant believes that all issues have been addressed and resolved above, wherefore applicant hereby respectfully requests favorable reconsideration and formal allowance.

Respectfully submitted,

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